

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BOEHRINGER INGELHEIM
PHARMACEUTICALS INC.,
BOEHRINGER INGELHEIM
INTERNATIONAL GMBH and
BOEHRINGER INGELHEIM PHARMA
GMBH & CO. KG,

Plaintiffs,

v.

BIOCON LIMITED, BIOCON PHARMA,
INC. AND BIOCON PHARMA LIMITED,

Defendants.

C.A. No. 25-523-CFC

ANDA CASE

DEFENDANT BIOCON'S ANSWER TO COMPLAINT

Defendants Biocon Limited, Biocon Pharma, Inc., and Biocon Pharma Limited (collectively, “Biocon”) by their counsel, hereby respond to the allegations set forth in Plaintiff Boehringer Ingelheim Pharmaceuticals Inc.’s Complaint against Defendant. (D.I. 1) Allegations not specifically admitted are denied.

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants’ submission of an Abbreviated New Drug Application (“ANDA”) to the Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of Plaintiffs’ TRADJENTA® (linagliptin) tablets prior to the expiration of United States Patent Nos. 8,853,156, 9,486,526, 10,034,877, and 11,911,388.

ANSWER TO PARAGRAPH 1:

Biocon admits that this action purports to arise under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, and purports to arise from Defendants’ submission of an Abbreviated New Drug Application (“ANDA”) to the

Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of Plaintiffs’ TRADJENTA® (linagliptin) tablets prior to the expiration of United States Patent Nos. 8,853,156, 9,486,526, 10,034,877, and 11,911,388. Biocon denies any remaining allegations in this paragraph.

THE PARTIES

2. Plaintiff Boehringer Ingelheim Pharmaceuticals Inc. (“BIP”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Rd., Ridgefield, CT 06877.

ANSWER TO PARAGRAPH 2:

Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint, and therefore denies them.

3. Plaintiff Boehringer Ingelheim International GmbH (“BII”) is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.

ANSWER TO PARAGRAPH 3:

Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 of the Complaint, and therefore denies them.

4. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG (“BIPKG”) is a limited liability partnership organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.

ANSWER TO PARAGRAPH 4:

Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 of the Complaint, and therefore denies them.

5. BIP, BII, and BIPKG are collectively referred to hereinafter as “Boehringer” or “Plaintiffs.”

ANSWER TO PARAGRAPH 5:

Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 of the Complaint, and therefore denies them.

6. On information and belief, Defendant Biocon Limited (“Biocon Ltd.”) is a company organized and existing under the laws of India, having a principal place of business at 20th KM, Hosur Road, Electronic City, Bengaluru, 560100, Karnataka, India.

ANSWER TO PARAGRAPH 6:

Biocon admits that Defendant Biocon Limited (“Biocon Ltd.”) is a company organized and existing under the laws of India, having a principal place of business at 20th KM, Hosur Road, Electronic City, Bengaluru, 560100, Karnataka, India. Biocon denies any remaining allegations in this paragraph.

7. On information and belief, Defendant Biocon Pharma Limited (“Biocon Pharma Ltd.”) is a company organized and existing under the laws of India, having a principal place of business at 20th KM, Hosur Road, Electronic City, Bengaluru, 560100, Karnataka, India.

ANSWER TO PARAGRAPH 7:

Biocon admits that Defendant Biocon Pharma Limited (“Biocon Pharma Ltd.”) is a company organized and existing under the laws of India, having a principal place of business at 20th KM, Hosur Road, Electronic City, Bengaluru, 560100, Karnataka, India. Biocon denies any remaining allegations in this paragraph.

8. On information and belief, Biocon Pharma Ltd. is a wholly owned subsidiary of Biocon Ltd.

ANSWER TO PARAGRAPH 8:

Biocon admits that Biocon Pharma Ltd. is a wholly owned subsidiary of Biocon Ltd. Biocon denies any remaining allegations in this paragraph.

9. On information and belief, Defendant Biocon Pharma, Inc. (“Biocon Pharma, Inc.”) is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at Harvard Business Services, Inc., 16192 Coastal Highway, Lewes, Delaware 19958, and having a principal place of business at 485 US-1 Building B, Iselin, NJ 08830.

ANSWER TO PARAGRAPH 9:

Biocon admits that Defendant Biocon Pharma, Inc. (“Biocon Pharma, Inc.”) is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at Harvard Business Services, Inc., 16192 Coastal Highway, Lewes, Delaware 19958, and having a principal place of business at 485 US-1 Building B, Iselin, NJ 08830. Biocon denies any remaining allegations in this paragraph.

10. On information and belief, Biocon Pharma, Inc. is a wholly owned subsidiary of Biocon Pharma Ltd. On information and belief, Biocon Ltd. is the ultimate parent company of Biocon Pharma, Inc. On information and belief, Biocon Pharma, Inc. is the United States agent for Biocon Ltd. and/or Biocon Pharma Ltd.

ANSWER TO PARAGRAPH 10:

Biocon admits that Biocon Pharma, Inc. is a wholly owned subsidiary of Biocon Pharma Ltd., and Biocon Ltd. is the parent company of Biocon Pharma, Inc. Biocon denies any remaining allegations in this paragraph.

11. On information and belief, Biocon Pharma, Inc. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, distributing, and/or importing generic pharmaceutical products throughout the United States, including in the State of Delaware, either directly or indirectly.

ANSWER TO PARAGRAPH 11:

Biocon admits that Biocon Pharma, Inc. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, distributing, and/or importing generic pharmaceutical products throughout the United States, including in the State of Delaware, either directly or indirectly. Biocon denies any remaining allegations in this paragraph.

12. On information and belief, the acts of Biocon Pharma, Ltd. and/or Biocon Pharma, Inc. complained of herein were done with the direction, cooperation, participation, and/or assistance of Biocon Ltd.

ANSWER TO PARAGRAPH 12:

Admitted.

13. Biocon Pharma, Inc., Biocon Pharma Ltd., and Biocon Ltd. are collectively referred to herein as "Biocon."

ANSWER TO PARAGRAPH 13:

Admitted.

14. On information and belief, Biocon Ltd. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within Delaware, through its own actions and through the actions of its agents and subsidiaries, including Biocon Pharma Ltd. and Biocon Pharma, Inc., from which Biocon Ltd. derives a substantial portion of its revenue.

ANSWER TO PARAGRAPH 14:

Biocon admits that, Biocon Ltd. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs. Biocon denies any remaining allegations in this paragraph.

15. On information and belief, Biocon Ltd. acted in concert with and directed Biocon Pharma Ltd. and/or Biocon Pharma, Inc. to prepare and submit ANDA No. 220117 (the "Biocon ANDA") for Biocon's 5 mg linagliptin product (the "Biocon ANDA Product"). On information and belief, if the FDA approves the Biocon ANDA, Biocon Ltd. will act in concert with and direct Biocon Pharma Ltd. and/or Biocon Pharma, Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Biocon ANDA Product in or into the United States, including Delaware.

ANSWER TO PARAGRAPH 15:

Admitted.

JURISDICTION AND VENUE

16. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 et seq., generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER TO PARAGRAPH 16:

Paragraph 16 states a conclusion of law to which no response is necessary. To the extent a response is required, Biocon denies the allegations in this paragraph.

17. Venue is proper in this Court because, among other things, Biocon Pharma, Inc. is incorporated in the State of Delaware and therefore “resides” in this judicial district, and Biocon has committed acts of infringement in this district. 28 U.S.C. § 1400(b). Biocon Ltd. and Biocon Pharma Ltd. are foreign corporations not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c). Moreover, Biocon has previously availed themselves of the legal protections of this district by, among other things, admitting or waiving objections to jurisdiction and/or asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. See, e.g., *Novo Nordisk, Inc. et al. v. Biocon Pharma Limited et al.*, C.A. 22-937 (D. Del.); *Novartis Pharms. Corp. v. Alkem Labs. Ltd. et al.*, C.A. No. 19-1979 (D. Del.); *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, C.A. No. 18-1043 (D. Del.); *Sanofi-Aventis U.S. LLC et al. v. Biocon Ltd.*, C.A. No. 17-3 (D. Del.); *Teva Pharms. USA, Inc., et al. v. Biocon Ltd. et al.*, C.A. No. 16-278 (D. Del.).

ANSWER TO PARAGRAPH 17:

Paragraph 17 states a conclusion of law to which no response is necessary. To the extent a response is required, Biocon denies the allegations in this paragraph.

PERSONAL JURISDICTION OVER BIOCON PHARMA, INC.

18. Plaintiffs reallege paragraphs 1-17 as if fully set forth herein.

ANSWER TO PARAGRAPH 18:

Biocon admits that Boehringer realleges paragraphs 1-17. Biocon denies any remaining allegations in this paragraph.

19. On information and belief, Biocon Pharma, Inc. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial

district.

ANSWER TO PARAGRAPH 19:

Denied.

20. This Court has personal jurisdiction over Biocon Pharma, Inc. because, inter alia, Biocon Pharma, Inc., on information and belief: (1) is incorporated in the State of Delaware; (2) has substantial, continuous, and systematic contacts with this judicial district; (3) makes its generic drug products available in this judicial district; (4) intends to market, sell, or distribute Biocon's ANDA Product to residents of this judicial district; (5) maintains a broad distributorship network within this judicial district; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this judicial district.

ANSWER TO PARAGRAPH 20:

Paragraph 20 states a conclusion of law to which no response is necessary. To the extent a response is required, Biocon Pharma, Inc. will not contest personal jurisdiction for the limited purpose of this action only. Biocon denies any remaining allegations in this paragraph.

21. Additionally, Biocon Pharma, Inc. has previously availed itself of the legal protections of the State of Delaware, by admitting or waiving objections to jurisdiction and/or asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. See, e.g., *Novo Nordisk, Inc. et al. v. Biocon Pharma Limited et al.*, C.A. 22-937 (D. Del.); *Novartis Pharms. Corp. v. Alkem Labs. Ltd. et al.*, C.A. No. 19-1979 (D. Del.); *Sanofi Aventis U.S. LLC et al. v. Biocon Ltd.*, C.A. No. 17-3 (D. Del.); *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, C.A. No. 18-1043 (D. Del.).

ANSWER TO PARAGRAPH 21:

Paragraph 21 states a conclusion of law to which no response is necessary. To the extent a response is required, Biocon Pharma, Inc. will not contest personal jurisdiction for the limited purpose of this action only. Biocon denies any remaining allegations in this paragraph.

PERSONAL JURISDICTION OVER BIOCON LTD.

22. Plaintiffs reallege paragraphs 1-21 as if fully set forth herein.

ANSWER TO PARAGRAPH 22:

Biocon admits that Boehringer realleges paragraphs 1-21. Biocon denies any remaining allegations in this paragraph.

23. On information and belief, Biocon Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER TO PARAGRAPH 23:

Denied.

24. This Court has personal jurisdiction over Biocon Ltd. because, *inter alia*, Biocon Ltd., on information and belief: (1) intends to market, sell, or distribute Biocon's ANDA Product to residents of this State; (2) controls Defendant Biocon Pharma, Inc., which is incorporated in the State of Delaware; (3) makes its generic drug products available in this State through Biocon Pharma, Inc., which is incorporated in the State of Delaware; (4) maintains a broad distributorship network within this State; and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

ANSWER TO PARAGRAPH 24:

Paragraph 24 states a conclusion of law to which no response is necessary. To the extent a response is required, Biocon Ltd will not contest personal jurisdiction for the limited purpose of this action only. Biocon denies any remaining allegations in this paragraph.

25. Additionally, Biocon Ltd. has previously availed itself of the legal protections of the State of Delaware, by admitting or waiving objections to jurisdiction and/or asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. See, e.g., *Novo Nordisk, Inc. et al. v. Biocon Pharma Limited, et al.*, C.A. 22-937 (D. Del.); *Novartis Pharms. Corp. v. Alkem Labs. Ltd. et al.*, C.A. No. 19-1979 (D. Del.); *Sanofi-Aventis U.S. LLC et al. v. Biocon Ltd.*, C.A. No. 17-3 (D. Del.); *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, C.A. No. 18-1043 (D. Del.); *Teva Pharms. USA, Inc., et al. v. Biocon Ltd. et al.*, C.A. No. 16-278 (D. Del.).

ANSWER TO PARAGRAPH 25:

Paragraph 25 states a conclusion of law to which no response is necessary. To the extent a response is required, Biocon Ltd will not contest personal jurisdiction for the limited purpose of

this action only. Biocon denies any remaining allegations in this paragraph.

26. Alternatively, to the extent the above facts do not establish personal jurisdiction over Biocon Ltd., this Court may exercise jurisdiction over Biocon Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Biocon Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Biocon Ltd. Has sufficient contacts with the United States as a whole, including, but not limited to, filing an ANDA with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Biocon Ltd. satisfies due process.

ANSWER TO PARAGRAPH 26:

Paragraph 26 states a conclusion of law to which no response is necessary. To the extent a response is required, Biocon Ltd will not contest personal jurisdiction for the limited purpose of this action only. Biocon denies any remaining allegations in this paragraph.

PERSONAL JURISDICTION OVER BIOCON PHARMA LTD.

27. Plaintiffs reallege paragraphs 1-26 as if fully set forth herein.

ANSWER TO PARAGRAPH 27:

Biocon admits that Boehringer realleges paragraphs 1-26. Biocon denies any remaining allegations in this paragraph.

28. On information and belief, Biocon Pharma Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER TO PARAGRAPH 28:

Denied.

29. This Court has personal jurisdiction over Biocon Pharma Ltd. because, *inter alia*, Biocon Pharma Ltd., on information and belief: (1) intends to market, sell, or distribute Biocon's ANDA Product to residents of this State; (2) controls Defendant Biocon Pharma, Inc., which is incorporated in the State of Delaware; (3) makes its generic drug products available in this State through Biocon Pharma, Inc., which is incorporated in the State of Delaware; (4) maintains a broad distributorship network within this State; and (5) enjoys substantial income from sales of its

generic pharmaceutical products in this State.

ANSWER TO PARAGRAPH 29:

Paragraph 29 states a conclusion of law to which no response is necessary. To the extent a response is required, Biocon Pharma Ltd. will not contest personal jurisdiction for the limited purpose of this action only. Biocon denies any remaining allegations in this paragraph.

30. Additionally, Biocon Pharma Ltd. has previously availed itself of the legal protections of the State of Delaware, by admitting or waiving objections to jurisdiction and/or asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. See, e.g., *Novo Nordisk, Inc. et al. v. Biocon Pharma Limited et al.*, C.A. 22-937 (D. Del.); *Novartis Pharms. Corp. v. Alkem Labs. Ltd. et al.*, C.A. No. 19-1979 (D. Del.); *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, C.A. No. 18-1043 (D. Del.).

ANSWER TO PARAGRAPH 30:

Paragraph 30 states a conclusion of law to which no response is necessary. To the extent a response is required, Biocon Pharma Ltd. will not contest personal jurisdiction for the limited purpose of this action only. Biocon denies any remaining allegations in this paragraph.

31. Alternatively, to the extent the above facts do not establish personal jurisdiction over Biocon Pharma Ltd., this Court may exercise jurisdiction over Biocon Pharma Ltd. Pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Biocon Pharma Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Biocon Pharma Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, filing an ANDA with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Biocon Pharma Ltd. satisfies due process.

ANSWER TO PARAGRAPH 31:

Paragraph 31 states a conclusion of law to which no response is necessary. To the extent a response is required, Biocon Pharma Ltd. will not contest personal jurisdiction for the limited purpose of this action only. Biocon denies any remaining allegations in this paragraph.

BACKGROUND

U.S. PATENT NO. 8,853,156

32. On October 7, 2014, the PTO duly and legally issued United States Patent No. 8,853,156 (the “156 Patent”) entitled “Treatment for Diabetes in Patients Inappropriate for Metformin Therapy” to inventors Klaus Dugi, Eva Ulrike Graefe-Mody, Ruth Harper, and Hans-Juergen Woerle. A true and correct copy of the ’156 Patent is attached as Exhibit 1.

ANSWER TO PARAGRAPH 32:

Biocon admits that on October 7, 2014, United States Patent No. 8,853,156 (the “156 Patent”) entitled “Treatment for Diabetes in Patients Inappropriate for Metformin Therapy” was issued. Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegation that Exhibit 1 contains a “true and correct copy of the ’156 Patent.” Biocon denies that the ’156 Patent was “duly and legally issued” and denies any remaining allegations in this paragraph.

U.S. PATENT NO. 9,486,526

33. On November 8, 2016, the PTO duly and legally issued United States Patent No. 9,486,526 (the “526 Patent”) entitled “Treatment for Diabetes in Patients Inappropriate for Metformin Therapy” to inventors Klaus Dugi, Eva Ulrike Graefe-Mody, Ruth Harper, and Hans-Juergen Woerle. A true and correct copy of the ’526 Patent is attached as Exhibit 2.

ANSWER TO PARAGRAPH 33:

Biocon admits that on November 8, 2016, United States Patent No. 9,486,526 (the “526 Patent”) entitled “Treatment for Diabetes in Patients Inappropriate for Metformin Therapy” was issued. Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegation that Exhibit 2 contains a “true and correct copy of the ’526 Patent.” Biocon denies that the ’526 Patent was “duly and legally issued” and denies any remaining allegations in this paragraph.

U.S. PATENT NO. 10,034,877

34. On July 31, 2018, the PTO duly and legally issued United States Patent No. 10,034,877 (the “877 Patent”) entitled “Treatment for Diabetes in Patients Inappropriate for Metformin Therapy” to inventors Klaus Dugi, Eva Ulrike Graefe-Mody, Ruth Harper, and Hans-Juergen Woerle. A true and correct copy of the ’877 Patent is attached as Exhibit 3.

ANSWER TO PARAGRAPH 34:

Biocon admits that on July 31, 2018, United States Patent No. 10,034,877 (the “877 Patent”) entitled “Treatment for Diabetes in Patients Inappropriate for Metformin Therapy” was issued. Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegation that Exhibit 3 contains a “true and correct copy of the ’877 Patent.” Biocon denies that the ’877 Patent was “duly and legally issued” and denies any remaining allegations in this paragraph.

U.S. PATENT NO. 11,911,388

35. On February 27, 2024, the PTO duly and legally issued United States Patent No. 11,911,388 (the “388 Patent”) entitled “Treatment for Diabetes in Patients with Insufficient Glycemic Control Despite Therapy with an Oral or Non-oral Antidiabetic Drug” to inventors Eva Ulrike Graefe-Mody, Thomas Klein, Michael Mark, and Hans-Juergen Woerle. A true and correct copy of the ’388 Patent is attached as Exhibit 4.

ANSWER TO PARAGRAPH 35:

Biocon admits that on February 27, 2024, United States Patent No. 11,911,388 (the “388 Patent”) entitled “Treatment for Diabetes in Patients with Insufficient Glycemic Control Despite Therapy with an Oral or Non-oral Antidiabetic Drug” was issued. Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegation that Exhibit 4 contains a “true and correct copy of the ’388 Patent.” Biocon denies that the ’388 Patent was “duly and legally issued” and denies any remaining allegations in this paragraph.

TRADJENTA®

36. BIPI is the holder of New Drug Application (“NDA”) No. 201280 (the “TRADJENTA® NDA”) for linagliptin, for oral use, in 5 mg dosage, which is sold under the trade name TRADJENTA®.

ANSWER TO PARAGRAPH 36:

Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 36 of the Complaint, and therefore denies them.

37. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '156 Patent is listed in the “Orange Book” with respect to TRADJENTA®.

ANSWER TO PARAGRAPH 37:

Biocon admits that, pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '156 Patent is listed in the “Orange Book” with respect to TRADJENTA®. Biocon denies any remaining allegations in this paragraph.

38. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '526 Patent is listed in the “Orange Book” with respect to TRADJENTA®.

ANSWER TO PARAGRAPH 38:

Biocon admits that, pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '526 Patent is listed in the “Orange Book” with respect to TRADJENTA®. Biocon denies any remaining allegations in this paragraph.

39. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '877 Patent is listed in the “Orange Book” with respect to TRADJENTA®.

ANSWER TO PARAGRAPH 39:

Biocon admits that, pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '877 Patent is listed in the “Orange Book” with respect to TRADJENTA®. Biocon denies any remaining allegations in this paragraph.

40. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '388 Patent is listed in the "Orange Book" with respect to TRADJENTA®.

ANSWER TO PARAGRAPH 40:

Biocon admits that, pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '388 Patent is listed in the "Orange Book" with respect to TRADJENTA®. Biocon denies any remaining allegations in this paragraph.

41. The '156 Patent covers the TRADJENTA® product and the use thereof.

ANSWER TO PARAGRAPH 41:

Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 41 of the Complaint, and therefore denies them.

42. The '526 Patent covers the TRADJENTA® product and the use thereof.

ANSWER TO PARAGRAPH 42:

Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 42 of the Complaint, and therefore denies them.

43. The '877 Patent covers the TRADJENTA® product and the use thereof.

ANSWER TO PARAGRAPH 43:

Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 43 of the Complaint, and therefore denies them.

44. The '388 Patent covers the TRADJENTA® product and the use thereof.

ANSWER TO PARAGRAPH 44:

Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 44 of the Complaint, and therefore denies them.

ACTS GIVING RISE TO THIS ACTION

45. Plaintiffs reallege paragraphs 1-44 as if fully set forth herein.

ANSWER TO PARAGRAPH 45:

Biocon admits that Boehringer realleges paragraphs 1-44. Biocon denies any remaining allegations in this paragraph.

46. On information and belief, Biocon submitted the Biocon ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Biocon ANDA Product.

ANSWER TO PARAGRAPH 46:

Biocon admits that it submitted the Biocon ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Biocon ANDA Product. Biocon denies any remaining allegations in this paragraph.

47. The Biocon ANDA refers to and relies upon the TRADJENTA® NDA and contains data that, according to Biocon, demonstrates the bioavailability or bioequivalence of the Biocon ANDA Product to TRADJENTA®.

ANSWER TO PARAGRAPH 47:

Biocon admits that the Biocon ANDA refers to and relies upon the TRADJENTA® NDA. Biocon admits that, according to Biocon, the ANDA contains data that demonstrates the bioavailability or bioequivalence of the Biocon ANDA Product to TRADJENTA®. Biocon denies any remaining allegations in this paragraph.

48. Plaintiffs received a letter from Biocon on or about March 18, 2025, stating that Biocon had included a certification in the Biocon ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, inter alia, certain claims of the '156, '526, '877, and '388 patents are invalid (the "Biocon Paragraph IV Certification"). The factual and legal bases in the letter does not dispute that Biocon will infringe at least one claim of each of the '156, '526, '877, and '388 Patents. Biocon intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Biocon ANDA Product prior to the expiration of the '156, '526, '877, and '388 Patents.

ANSWER TO PARAGRAPH 48:

Biocon admits that Plaintiffs received a letter from Biocon on or about March 18, 2025, stating that Biocon had included a certification in the Biocon ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '156, '526, '877, and '388 patents are invalid (the “Biocon Paragraph IV Certification”). Biocon denies the remaining allegations in this paragraph, including but not limited to any characterization of the factual and legal bases in the letter, any assertion that the letter does not dispute infringement, and any assertion regarding Biocon's intent to engage in commercial activities prior to expiration.

49. Biocon's Paragraph IV letter includes very limited information about the nature and form of the Biocon ANDA Product, including little to no information regarding how the Biocon ANDA Product is manufactured or the amounts and ingredients of such Product.

ANSWER TO PARAGRAPH 49:

Biocon admits that its Paragraph IV letter included information about the nature and form of the Biocon ANDA Product. Biocon denies the remaining allegations in this paragraph, including any characterization of the extent or sufficiency of the information provided regarding manufacturing, amounts, or ingredients.

50. The Biocon Paragraph IV Certification offered confidential access to unspecified portions of the Biocon ANDA (“Offer of Confidential Access” or “OCA”) on terms and conditions set by Biocon. Biocon requested that Boehringer accept the terms of the OCA before receiving access to the unspecified portions of the Biocon ANDA.

ANSWER TO PARAGRAPH 50:

Biocon admits that the Biocon Paragraph IV Certification offered confidential access to portions of the Biocon ANDA (“Offer of Confidential Access” or “OCA”) and that Biocon requested that Boehringer accept the terms of the OCA before receiving access. Biocon denies any remaining allegations in this paragraph.

51. Under 21 U.S.C. § 355(c)(3)(D)(i)(III), an offer of confidential access “shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information.”

ANSWER TO PARAGRAPH 51:

Biocon admits that under 21 U.S.C. § 355(c)(3)(D)(i)(III), an offer of confidential access “shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information.” Biocon denies any remaining allegations in this paragraph.

52. The OCA contained unreasonable restrictions, above and beyond those that would apply under a protective order, on who could view the Biocon ANDA. For example, the OCA did not offer access to the entire Biocon ANDA and did not permit any access by Boehringer’s inhouse counsel. The OCA also did not grant access to the Drug Master File (“DMF”) that supports the Biocon ANDA or samples of the Biocon ANDA Product.

ANSWER TO PARAGRAPH 52:

Denied.

53. After receiving the Biocon Paragraph IV Certification, Boehringer negotiated with Biocon to obtain a copy of the Biocon ANDA under terms “as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information.” Boehringer also attempted to negotiate access to samples of the Biocon ANDA Product and the DMF related to the Biocon ANDA Product.

ANSWER TO PARAGRAPH 53:

Biocon admits that after receiving the Biocon Paragraph IV Certification, Boehringer negotiated with Biocon regarding access to the Biocon ANDA. Biocon denies any characterization of the purpose or nature of these negotiations beyond the exchange of proposals. Biocon denies any remaining allegations in this paragraph.

54. On March 27, 2025, Boehringer requested access to the complete Biocon ANDA,

the DMF, and samples of the Biocon ANDA Product. Boehringer also requested that Biocon modify its OCA to permit access by certain in-house counsel at Boehringer. The parties then exchanged multiple emails and letters regarding the terms of Biocon's OCA on April 2, 6, 8, 9, and 14. During these negotiations, Boehringer made multiple compromise proposals.

ANSWER TO PARAGRAPH 54:

Biocon admits that on March 27, 2025, Boehringer requested access to the complete Biocon ANDA, the DMF, and samples of the Biocon ANDA Product, and requested that Biocon modify its OCA to permit access by certain in-house counsel at Boehringer. Biocon admits that the parties exchanged multiple emails and letters regarding the terms of Biocon's OCA on April 2, 6, 8, 9, and 14. Biocon admits that Boehringer made compromise proposals. Biocon denies any remaining allegations in this paragraph, including any characterization of the nature or reasonableness of the proposals.

55. On April 17, 2025, Biocon agreed to provide Boehringer access to the complete Biocon ANDA under negotiated OCA terms. Biocon sent Boehringer the updated OCA for execution on April 21, 2025. Boehringer returned to Biocon the fully executed OCA the same day. Biocon provided Boehringer access to the complete Biocon ANDA on April 22, 2025. On April 25, 2025, Biocon provided a replacement for certain corrupted files in Biocon's April 22 production. Biocon refused to provide any access by Boehringer to the DMF or samples of the Biocon ANDA Product.

ANSWER TO PARAGRAPH 55:

Biocon admits that on April 17, 2025, Biocon agreed to provide Boehringer access to the complete Biocon ANDA under negotiated OCA terms. Biocon admits that Biocon sent Boehringer the updated OCA for execution on April 21, 2025, and Boehringer returned the fully executed OCA the same day. Biocon admits it provided Boehringer access to the complete Biocon ANDA on April 22, 2025, and on April 25, 2025, provided a replacement for certain corrupted files. Biocon admits it refused to provide any access to the DMF or samples of the Biocon ANDA Product, as such provision is not required by statute. Biocon denies any remaining allegations in this paragraph.

56. Under the Hatch-Waxman Act, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter in order to receive certain benefits under the Act, including a stay of approval of the generic drug for 30 months during the pendency of litigation, as appropriate. 21 U.S.C. § 355 (c)(3)(c). Biocon's refusal to produce its DMF and samples of the Biocon ANDA Product, and its unreasonable delay in providing the complete Biocon ANDA has hindered Boehringer's ability to consider information that is relevant to its infringement analysis of the '156, '526, '877, and '388 Patents. See *Hoffman-La Roche, Inc. v. Invamed, Inc.*, 213 F.3d 1359, 1363–64 (Fed. Cir. 2000).

ANSWER TO PARAGRAPH 56:

Biocon admits that under the Hatch-Waxman Act, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter in order to receive certain benefits under the Act, including a stay of approval of the generic drug for 30 months during the pendency of litigation, as appropriate, pursuant to 21 U.S.C. § 355(c)(3)(c). Biocon denies that its refusal to produce its DMF and samples of the Biocon ANDA Product, or any alleged delay in providing the complete Biocon ANDA, hindered Boehringer's ability to consider information relevant to its infringement analysis. Biocon denies any remaining allegations in this paragraph, including any reliance on *Hoffman-La Roche, Inc. v. Invamed, Inc.*

57. Provided here as a representative claim for exemplary purposes, claim 1 of the '156 Patent recites: "1. A method of treating and/or preventing metabolic diseases in a patient for whom metformin therapy is inappropriate due to at least one contraindication against metformin comprising orally administering to the patient a DPP-IV inhibitor wherein the contraindication is selected from the group consisting of: renal disease, renal impairment or renal dysfunction, unstable or acute congestive heart failure, acute or chronic metabolic acidosis, and hereditary galactose intolerance," and claim 10 of the '156 Patent recites: "The method according to claim 1 wherein the metabolic disorder is type 2 diabetes mellitus and wherein the contraindication is renal disease, renal impairment or renal dysfunction, and wherein said DPP-4 inhibitor is used for said patient in the same dose as for a patient with normal renal function."

ANSWER TO PARAGRAPH 57:

Biocon admits that paragraph 57 purports to provide representative claims for exemplary purposes. Biocon refers to the '156 Patent for its complete and accurate contents. Biocon denies any remaining allegations in this paragraph.

58. On information and belief, the Biocon ANDA Product, when used in accordance with the instructions provided in the prescribing label included in the Biocon ANDA, will cause healthcare providers or clinicians to practice a method of treating and/or preventing type 2 diabetes mellitus in a patient for whom metformin therapy is inappropriate due to renal disease, renal impairment or renal dysfunction by administering an oral dose of linagliptin to the patient in the same dose as for a patient with normal renal function.

ANSWER TO PARAGRAPH 58:

Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 58 of the Complaint, and therefore denies them.

59. Provided here as a representative claim for exemplary purposes, claim 1 of the '526 Patent recites: "A method for treating and/or preventing type 2 diabetes mellitus in a patient having moderate or severe chronic renal impairment or end-stage renal disease comprising orally administering to the patient a DPP-4 inhibitor, which is 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine or a pharmaceutically acceptable salt thereof, wherein said DPP-4 inhibitor is administered in an oral dose of 5 mg per day to said patient, wherein metformin therapy for said patient is ineligible due to contraindication against metformin."

ANSWER TO PARAGRAPH 59:

Biocon admits that paragraph 59 purports to provide a representative claim for exemplary purposes. Biocon refers to the '526 Patent for its complete and accurate contents. Biocon denies any remaining allegations in this paragraph.

60. On information and belief, the Biocon ANDA Product, when used in accordance with the instructions provided in the prescribing label included in the Biocon ANDA, will cause healthcare providers or clinicians to practice a method for treating and/or preventing type 2 diabetes mellitus in patients with moderate or severe chronic renal impairment or end-stage renal disease by administering an oral 5 mg dose per day of linagliptin to the patient that is ineligible for metformin due to contraindication against metformin.

ANSWER TO PARAGRAPH 60:

Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 60 of the Complaint, and therefore denies them.

61. Provided here as a representative claim for exemplary purposes, claim 1 of the '877

Patent recites: “A method of treating metabolic diseases in a patient for whom metformin therapy is inappropriate due to at least one contraindication against metformin comprising orally administering to the patient 5 mg of 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine per day wherein the contraindication is selected from the group consisting of: renal disease, renal impairment or renal dysfunction, unstable or acute congestive heart failure, acute or chronic metabolic acidosis, and hereditary galactose intolerance, wherein no adjustment of the daily dose is required for 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in a patient with mild, moderate or severe renal impairment or end-stage renal disease.”

ANSWER TO PARAGRAPH 61:

Biocon admits that paragraph 61 purports to provide a representative claim for exemplary purposes. Biocon refers to the '877 Patent for its complete and accurate contents. Biocon denies any remaining allegations in this paragraph.

62. On information and belief, the Biocon ANDA Product, when used in accordance with the instructions provided in the prescribing label included in the Biocon ANDA, will cause healthcare providers or clinicians to practice a method for treating and/or preventing metabolic diseases in a patient with renal disease, renal impairment, or renal dysfunction for whom metformin therapy is inappropriate, by administering linagliptin without dose adjustment.

ANSWER TO PARAGRAPH 62:

Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 62 of the Complaint, and therefore denies them.

63. Provided here as a representative claim for exemplary purposes, claim 1 of the '388 Patent recites: “1. A method for treating metabolic diseases in type 2 diabetes patients with renal impairment and with insufficient glycemic control despite either metformin monotherapy or therapy with metformin in combination with an insulin or an insulin analogue, the method comprising administering a DPP-4 inhibitor which is 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, or a pharmaceutically acceptable salt thereof, in an oral daily amount of 5 mg, wherein said 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, or a pharmaceutically acceptable salt thereof, is used in combination with either metformin monotherapy or metformin in combination with an insulin or an insulin analogue.”

ANSWER TO PARAGRAPH 63:

Biocon admits that paragraph 63 purports to provide a representative claim for exemplary

purposes. Biocon refers to the '388 Patent for its complete and accurate contents. Biocon denies any remaining allegations in this paragraph.

64. On information and belief, the Biocon ANDA Product, when used in accordance with the instructions provided in the prescribing labels included in the Biocon ANDA, will cause healthcare providers or clinicians to practice a method of treating metabolic diseases in type 2 diabetes patients with renal impairment and with insufficient glycemic control despite either metformin monotherapy or therapy with metformin in combination with an insulin or an insulin analogue by administering linagliptin.

ANSWER TO PARAGRAPH 64:

Biocon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 64 of the Complaint, and therefore denies them.

COUNT I — INFRINGEMENT OF THE '156 PATENT

65. Plaintiffs reallege paragraphs 1-64 as if fully set forth herein.

ANSWER TO PARAGRAPH 65:

Biocon admits that Boehringer realleges and incorporates by reference its responses to paragraphs 1-64 as if fully set forth herein. Biocon denies any remaining allegations in this paragraph.

66. Biocon has infringed at least one claim of the '156 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Biocon ANDA, by which Biocon seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Biocon ANDA Product prior to the expiration of the '156 Patent.

ANSWER TO PARAGRAPH 66:

Biocon denies that it has infringed, or will infringe, directly or indirectly, or contributed to or induced infringement of, at least one claim of the '156 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Biocon ANDA. Biocon denies any remaining allegations in this paragraph.

67. Biocon has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Biocon ANDA Product in the event that the FDA approves the Biocon ANDA. Accordingly, an actual and immediate controversy exists regarding Biocon's infringement of the '156 Patent under 35 U.S.C. § 271 (b).

ANSWER TO PARAGRAPH 67:

Denied.

68. Biocon's manufacture, use, offer to sell, or sale of the Biocon ANDA Product in the United States or importation of the Biocon ANDA Product into the United States during the term of the '156 Patent would further infringe at least one claim of the '156 Patent under 35 U.S.C. § 271 (b).

ANSWER TO PARAGRAPH 68:

Denied.

69. On information and belief, the Biocon ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '156 Patent either literally or under the doctrine of equivalents.

ANSWER TO PARAGRAPH 69:

Denied.

70. On information and belief, Biocon had knowledge of the '156 Patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '156 Patent, either literally or under the doctrine of equivalents.

ANSWER TO PARAGRAPH 70:

Denied.

71. On information and belief, the offering to sell, sale, and/or importation of the Biocon ANDA Product by Biocon would actively induce infringement of at least one of the claims of the '156 Patent, either literally or under the doctrine of equivalents.

ANSWER TO PARAGRAPH 71:

Denied.

72. Plaintiffs will be substantially and irreparably harmed if Biocon is not enjoined from infringing the '156 Patent.

ANSWER TO PARAGRAPH 72:

Denied.

73. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

ANSWER TO PARAGRAPH 73:

Denied.

74. On information and belief, based on the information provided by Biocon to date, the factual contentions in paragraph 45-73 have evidentiary support. On information and belief, the factual contentions in paragraphs 45-73 will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

ANSWER TO PARAGRAPH 74:

Denied.

COUNT II — INFRINGEMENT OF THE '526 PATENT

75. Plaintiffs reallege paragraphs 1-74 as if fully set forth herein.

ANSWER TO PARAGRAPH 75:

Biocon admits that Boehringer realleges and incorporates by reference its responses to paragraphs 1-74 as if fully set forth herein. Biocon denies any remaining allegations in this paragraph.

76. Biocon has infringed at least one claim of the '526 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Biocon ANDA, by which Biocon seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Biocon ANDA Product prior to the expiration of the '526 Patent.

ANSWER TO PARAGRAPH 76:

Denied.

77. Biocon has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Biocon ANDA Product in the event that the FDA approves the Biocon ANDA. Accordingly, an actual and immediate controversy exists regarding Biocon's infringement of the '526 Patent under 35 U.S.C. § 271 (b).

ANSWER TO PARAGRAPH 77:

Denied.

78. Biocon's manufacture, use, offer to sell, or sale of the Biocon ANDA Product in the United States or importation of the Biocon ANDA Product into the United States during the term of the '526 Patent would further infringe at least one claim of the '526 Patent under 35 U.S.C. § 271 (b).

ANSWER TO PARAGRAPH 78:

Denied.

79. On information and belief, the Biocon ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '526 Patent either literally or under the doctrine of equivalents.

ANSWER TO PARAGRAPH 79:

Denied.

80. On information and belief, Biocon had knowledge of the '526 Patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '526 Patent, either literally or under the doctrine of equivalents.

ANSWER TO PARAGRAPH 80:

Denied.

81. On information and belief, the offering to sell, sale, and/or importation of the Biocon ANDA Product by Biocon would actively induce infringement of at least one of the claims of the '526 Patent, either literally or under the doctrine of equivalents.

ANSWER TO PARAGRAPH 81:

Denied.

82. Plaintiffs will be substantially and irreparably harmed if Biocon is not enjoined from infringing the '526 Patent.

ANSWER TO PARAGRAPH 82:

Denied.

83. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

ANSWER TO PARAGRAPH 83:

Denied.

84. On information and belief, based on the information provided by Biocon to date, the factual contentions in paragraph 75-83 have evidentiary support. On information and belief, the factual contentions in paragraphs 75-83 will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

ANSWER TO PARAGRAPH 84:

Denied.

COUNT III — INFRINGEMENT OF THE '877 PATENT

85. Plaintiffs reallege paragraphs 1-84 as if fully set forth herein.

ANSWER TO PARAGRAPH 85:

Biocon admits that Boehringer realleges and incorporates by reference its responses to paragraphs 1-84 as if fully set forth herein. Biocon denies any remaining allegations in this paragraph.

86. Biocon has infringed at least one claim of the '877 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Biocon ANDA, by which Biocon seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Biocon ANDA Product prior to the expiration of the '877 Patent.

ANSWER TO PARAGRAPH 86:

Denied.

87. Biocon has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Biocon ANDA Product in the event that the FDA approves the Biocon ANDA. Accordingly, an actual and immediate controversy exists regarding Biocon's infringement of the '877 Patent under 35 U.S.C. § 271 (b).

ANSWER TO PARAGRAPH 87:

Denied.

88. Biocon's manufacture, use, offer to sell, or sale of the Biocon ANDA Product in the United States or importation of the Biocon ANDA Product into the United States during the term of the '877 Patent would further infringe at least one claim of the '877 Patent under 35 U.S.C. § 271 (b).

ANSWER TO PARAGRAPH 88:

Denied.

89. On information and belief, the Biocon ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '877 Patent either literally or under the doctrine of equivalents.

ANSWER TO PARAGRAPH 89:

Denied.

90. On information and belief, Biocon had knowledge of the '877 Patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '877 Patent, either literally or under the doctrine of equivalents.

ANSWER TO PARAGRAPH 90:

Denied.

91. On information and belief, the offering to sell, sale, and/or importation of the Biocon ANDA Product by Biocon would actively induce infringement of at least one of the claims of the '877 Patent, either literally or under the doctrine of equivalents.

ANSWER TO PARAGRAPH 91:

Denied.

92. Plaintiffs will be substantially and irreparably harmed if Biocon is not enjoined from infringing the '877 Patent.

ANSWER TO PARAGRAPH 92:

Denied.

93. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

ANSWER TO PARAGRAPH 93:

Denied.

94. On information and belief, based on the information provided by Biocon to date, the factual contentions in paragraph 85-93 have evidentiary support. On information and belief, the factual contentions in paragraphs 85-93 will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

ANSWER TO PARAGRAPH 94:

Denied.

COUNT IV — INFRINGEMENT OF THE '388 PATENT

95. Plaintiffs reallege paragraphs 1-94 as if fully set forth herein.

ANSWER TO PARAGRAPH 95:

Biocon admits that Boehringer realleges and incorporates by reference its responses to paragraphs 1-94 as if fully set forth herein. Biocon denies any remaining allegations in this paragraph.

96. Biocon has infringed at least one claim of the '388 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Biocon ANDA, by which Biocon seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Biocon ANDA Product prior to the expiration of the '388 Patent.

ANSWER TO PARAGRAPH 96:

Denied.

97. Biocon has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Biocon ANDA Product in the event that the FDA approves the Biocon ANDA. Accordingly, an actual and immediate controversy exists regarding Biocon's infringement of the '388 Patent under 35 U.S.C. § 271 (b).

ANSWER TO PARAGRAPH 97:

Denied.

98. Biocon's manufacture, use, offer to sell, or sale of the Biocon ANDA Product in the United States or importation of the Biocon ANDA Product into the United States during the term of the '388 Patent would further infringe at least one claim of the '388 Patent under 35 U.S.C. § 271 (b).

ANSWER TO PARAGRAPH 98:

Denied.

99. On information and belief, the Biocon ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '388 Patent either literally or under the doctrine of equivalents.

ANSWER TO PARAGRAPH 99:

Denied.

100. On information and belief, Biocon had knowledge of the '388 Patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '388 Patent, either literally or under the doctrine of equivalents.

ANSWER TO PARAGRAPH 100:

Denied.

101. On information and belief, the offering to sell, sale, and/or importation of the Biocon ANDA Product by Biocon would actively induce infringement of at least one of the claims of the '388 Patent, either literally or under the doctrine of equivalents.

ANSWER TO PARAGRAPH 101:

Denied.

102. Plaintiffs will be substantially and irreparably harmed if Biocon is not enjoined from infringing the '388 Patent.

ANSWER TO PARAGRAPH 102:

Denied.

103. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

ANSWER TO PARAGRAPH 103:

Denied.

104. On information and belief, based on the information provided by Biocon to date, the factual contentions in paragraph 95-103 have evidentiary support. On information and belief, the factual contentions in paragraphs 95-103 will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

ANSWER TO PARAGRAPH 104:

Denied.

105. The foregoing factual contentions in paragraphs 1-104 have evidentiary support, or likely will have evidentiary support after a reasonable opportunity for further investigation and discovery.

ANSWER TO PARAGRAPH 105:

Denied.

PRAYER FOR RELIEF

Biocon denies that Plaintiffs are entitled to any of the relief sought in their Request for Relief.

ADDITIONAL DEFENSES

Further to answering the Complaint, and as additional defenses thereto, Biocon asserts the following additional defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. An allegation of any defense

below is not an admission that Biocon bears the burden of proof or persuasion on any claim or issue.

FIRST ADDITIONAL DEFENSE – NON-INFRINGEMENT

Biocon has not infringed, is not infringing, will not infringe, will not induce to infringe, and will not contribute to infringement of, literally or under the doctrine of equivalents, any valid and enforceable claim of U.S. Patent Nos. 8,853,156, 9,486,526, 10,034,877, and 11,911,388.

SECOND ADDITIONAL DEFENSE – INVALIDITY OR UNENFORCEABILITY

The claims of U.S. Patent Nos. 8,853,156, 9,486,526, 10,034,877, and 11,911,388 are invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, 112, and 116, and/or for double patenting.

THIRD ADDITIONAL DEFENSE – PROSECUTION HISTORY ESTOPPEL

Plaintiffs' claims are barred, in whole or in part, by the doctrine of prosecution history estoppel. The claims of U.S. Patent Nos. 8,853,156, 9,486,526, 10,034,877, and 11,911,388 asserted against Biocon are so limited as not to cover the manufacture, use, sale, offer for sale, or importation of the proposed ANDA products described in Biocon's ANDA due to the arguments, statements, representations, and/or amendments made by Plaintiffs to the United States Patent and Trademark Office during the prosecution of the applications leading to issuance of the asserted patents.

FOURTH ADDITIONAL DEFENSE – FAILURE TO STATE A CLAIM

Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

RESERVATION OF ADDITIONAL DEFENSES

Biocon reserves the right to assert such other defenses, counterclaims, and/or reductions in

damages, if such defenses, counterclaims, or reductions in damages are discovered during the course of this litigation or otherwise.

BIOCON'S PRAYER FOR RELIEF

WHEREFORE, Defendants respectfully pray that this Court enter judgment in Defendants' favor and grant the following relief:

- a. Dismiss Plaintiffs' Complaint with prejudice and deny each and every prayer for relief contained therein;
- b. A declaration that Biocon does not infringe the claims of the patents asserted against Biocon;
- c. A declaration that the claims of the patents asserted against Biocon are invalid or unenforceable;
- d. Award the costs of this action against Plaintiffs;
- e. A declaration that this is not an exceptional case within the meaning of 35 U.S.C. § 285, and that Plaintiffs are not entitled to recover reasonable attorney fees and costs;
- f. A declaration that the effective date of any FDA approval of Biocon's proposed ANDA product shall not be stayed thirty months from the date of its Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii); and
- g. An award to Biocon of such further and other relief as this Court deems necessary, just, and proper.

Dated: July 28, 2025

SMITH, KATZENSTEIN & JENKINS LLP

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